

NDA 20-812/S-007

Whitehall-Robins Healthcare
Attention: Sharon Heddish
Vice President, Regulatory Affairs - Worldwide
Five Giralda Farms
Madison, NJ 07940-0871

SEP 7 2000

Dear Ms. Heddish:

Please refer to your supplemental new drug application dated October 26, 1999, received October 28, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pediatric Advil (ibuprofen) Drops, 100 mg/2.5 mL.

This "Changes Being Effected" supplemental new drug application provides for revised labeling to implement the allergy alert statements required by our September 15, 1998 letter.

We have completed the review of this supplemental new drug application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling submitted on October 26, 1999. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

We request that the labeling for this drug product, be revised to comply with the requirements of 21 CFR 201.3 15 (sore throat warning) and 21 CFR 369.20 (general warning regarding accidental overdose by children) within 180 days or at the next printing, whichever comes first. In addition, please delete the period after the bulleted statement, "**Do not use**" on the bottle label.

We note that the labeling was not submitted in Drug Facts format consistent with the requirements of the March 17, 1999 FEDERAL REGISTER document "Over-the-Counter Human Drugs; Labeling Requirements; Final Rule" (64 FR 13254) (OTC labeling final rule), which has been incorporated into the regulations at 21 CFR 201.66. We remind you that the labeling of your product must be revised to reflect the Drug Facts format within the timeframes specified in the OTC labeling final rule.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we

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request that you submit a copy of the letter to this NDA and a copy to the following address:

MED WATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions regarding this application, please contact Thomas Parmelee, Pharm.D., Regulatory Project Manager, at 301-827-2271.

Sincerely,

Linda M. Katz, M.D.,
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Pediatric Advil Drops

IBUPROFEN ORAL SUSPENSION

Fever Reducer/Pain Reliever

Do not use if breakable ring on bottle cap is separated

 Grape Flavor

For Ages 2-3

Pediatric Advil Drops

IBUPROFEN ORAL SUSPENSION
100 mg per 2.5 mL (1/2 teaspoon)

Fever Reducer/Pain Reliever

Lasts up to 8 Hours



GRAPE-FLAVORED
DROPS
Alcohol Free



1/2 FL OZ (15 mL)

Pediatric Advil Drops

IBUPROFEN ORAL SUSPENSION
100 mg per 2.5 mL (1/2 teaspoon)
Fever Reducer/Pain Reliever

 Questions or Comments?
Call toll-free 1-800-88-ADVIL.
Or ask your pharmacist, doctor or health care professional.

Other information

• store at 20-25°C (68-77°F)
• see bottom of box for lot number and expiration date

Inactive ingredients artificial flavor, carboxymethylcellulose sodium, citric acid, edetate disodium, FD&C Red No. 40, FD&C Blue No. 1, glycerin, microcrystalline cellulose, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum.

Long Lasting: Up to 8 hours of fever relief.

Great Convenience: Long duration means fewer doses needed per day.

Whitehall-Robins Healthcare
Madison, NJ 07940
Made in USA



SEP 7 2000

Important: Read all product information before using. Keep this box for important information. This product is intended for use in children ages 2-3 years.

Active ingredient Ibuprofen 100 mg per 2.5 mL **Purposes** Fever reducer/pain reliever

Uses temporarily:

- reduces fever
- relieves minor aches and pains due to common cold, flu, sore throat, headaches and toothaches

Directions

1. Use this product only with chart provided.
2. Find right dose on chart below. If possible, use weight to dose. Otherwise, use age.
3. Measure dose with the dosing device provided. Do not discard dosing device.
4. Repeat dose every 6-8 hours, if needed.
5. Do not use more than 4 times a day.
6. If stomach upset occurs while taking this product, give with food or milk.

Shake Well Before Using

Weight (lb)	Age (yr)	Dose (mL)
Under 24	Under 2	Consult Doctor
24-35	2-3	2.5 mL

One Dose Lasts 6-8 Hours

Warnings

Allergy alert: ibuprofen may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- if your child has problems or serious side effects from taking fever reducers/pain relievers
- if your child is dehydrated (significant fluid loss) due to continued vomiting, diarrhea, or lack of fluid intake
- if breakable ring on bottle cap is separated

(See Side Panel for Additional Warnings)→

Pediatric Advil Drops

IBUPROFEN ORAL SUSPENSION
100 mg per 2.5 mL (1/2 teaspoon)
Fever Reducer/Pain Reliever

Warnings (continued)

Ask a doctor before use if your child

- is under a doctor's care for any serious condition or is taking any other drug
- has redness or swelling present in the painful area
- is taking any other product that contains ibuprofen, or any other pain reliever/fever reducer
- has stomach pain

Stop and ask a doctor if

- an allergic reaction occurs. Seek medical help right away
- fever or pain lasts for more than 3 days
- your child does not get any relief within the first day (24 hours) of treatment or pain or fever gets worse
- stomach upset gets worse or lasts
- sore throat is severe, lasts for more than 2 days or occurs with fever, headache, rash, nausea or vomiting
- any new symptoms appear

Keep out of reach of children. In case of overdose, seek professional assistance or contact a poison control center right away.